BEFORE THE

FEDERAL COMMUNICATIONS COMMISSION

WASHINGTON, DC 20554

In the Matter of	
Investigation of the Spectrum Requirements for Advanced Medical Technologies	ET Docket No. 06-135
Amendment of Parts 2 and 95 of the Commission's Rules To Establish The Medical Data Service at 401-402 and 405-406 MHz	RM-11271

COMMENTS OF MEDTRONIC, INC.

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SUMMARY

"[T]he health care industry has reached the beginning of a wave of breakthroughs in providing care and rehabilitation that will use radiocommunication technologies in a variety of ways." MedRadio NPRM at ¶ 36. Medtronic and other innovative medical device manufacturers are developing an increasing number of "sophisticated devices … to monitor various health conditions and to control the medication for a wide variety of ailments and diseases, leading to better management of these conditions to reduce their morbidity, their effects on overall health, and [improve] patients' quality of life and life expectancy." *Id*. To support this need, the FCC's proposal to allocate two 1 MHz bands directly adjacent to the Medical Implant Communications Service ("MICS") at 402-405 MHz for low-power body-worn and implanted medical devices is timely indeed.

The new MedRadio service will advance the Commission's objective of encouraging "the provision of new technologies and services to the public" as set forth in Section 7 of the Communications Act, *see* 47 U.S.C. § 157, and further the Administration's efforts to improve healthcare through expanded use of information technology. Few spectrum uses are more important than supporting new medical technologies that can improve and extend lives. Accordingly, the FCC should promptly authorize operation of the next generation of RF medical devices in accordance with the proposals set forth in the NPRM.

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Medtronic, Inc., is pleased to provide the FCC with these opening comments on the Notice of Proposed Rulemaking in the above-referenced proceedings. First and foremost, Medtronic applauds the Commission for proposing to allocate the 401-402 and 405-406 MHz bands to "accommodate the development and use of a variety of new medical devices that rely on radiocommunication for critical aspects of their functionality."[1]

As set forth by the FCC in the MedRadio NPRM,[2] the additional spectrum allocation will support short-range wireless medical connectivity among a broad range of body-worn sensors,

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[1] *Investigation of the Spectrum Requirements for Advanced Medical Technologies*, ET Docket No. 06-136, *Amendment of Parts 2 and 95 of the Commission's Rules To Establish The Medical Data Service at 401-402 and 405-406 MHz*, RM-11271, Notice of Proposed Rulemaking, Notice of Inquiry, and Order, FCC 06-103 at ¶ 1 (July 18, 2006) ("MedRadio NPRM").

[2] *See* MedRadio NPRM at ¶ 1 n.1 citing Petition for Rulemaking filed by Medtronic, July 15, 2005, which initiated RM-11271.

implanted medical devices, and external monitoring and control equipment in hospital rooms, physicians' offices, assisted living facilities, and patient homes.[3] Such wireless medical connectivity will enhance patient quality of life, improve the level of medical care, and substantially lower healthcare costs.[4] Accordingly, Medtronic urges the FCC to promptly allocate the additional spectrum proposed in the MedRadio NPRM to enable the next generation of wireless medical applications.

I. ADDITIONAL SPECTRUM IS NEEDED TO ACCOMMODATE PRESENT NEEDS AND FUTURE ADVANCES IN IMPLANTED AND BODY-WORN WIRELESS MEDICAL TECHNOLOGY.

As the FCC correctly recognizes, given the nature and pace of development of novel and more capable medical technologies, there is a pressing need for additional frequency spectrum to accommodate new therapeutic and diagnostic concepts in implanted and body-worn medical radio devices.[5] For example, implanted devices that "treat severe chronic depression" and "[t]remors related to Parkinson's disease are available today."[6] Soon, medical devices that allow "paralyzed individuals to control artificial limbs by thought through wireless interfaces between brain, nerve and muscle" will be commonplace.[7] Over the coming decades, the range of medical

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[3] *See* MedRadio NPRM at ¶¶ 1-5.

[4] *See* MedRadio NPRM at ¶¶ 1, 23.

[5] *See* MedRadio NPRM at ¶ 3.

[6] MedRadio NPRM at ¶ 1. *See* Chappell Brown, *Real-World Implants Are Arriving*, EE TIMES, Sept. 12, 2005, *available at* http://www.eetimes.com/news/latest/showArticle.jhtml?articleID=170701430 *last accessed* Oct. 31, 2006 ("[E]lectrodes that can be implanted and communicate with the nervous system are being used in products marketed by Medtronic Inc. (Minneapolis). Applications include controlling Parkinson's tremors, alleviating pain and controlling heart rhythms … .").

[7] *See* MedRadio NPRM at ¶ 1.

device applications that incorporate short-range wireless capabilities necessarily will expand to meet the needs of our aging population.

The proposed MedRadio allocation will enable remote communication of patient medical data – often referred to as "Telemedicine" – to provide patients with access to "medical specialists in a variety of practices, including cardiology, pediatrics, and radiology, without leaving their homes or communities."[8] Such communications capabilities will allow physicians to consult with and treat patients remotely, provide improved need-based care to patients generally, and particularly benefit those who live in remote areas of the country and have difficulty traveling to medical facilities for treatment. Also, telemedicine allows a patient to forego a trip to the physician's office if the data show that conditions are normal, directly reducing healthcare costs and benefiting the economy.[9] Furthermore, because physicians will have increased access to medical data from patients who are remotely monitored, patients that do travel into the physician's office will experience less office "down time" and increased "quality time."[10]

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[8] *See* Rural Health Care Support Mechanism, *Order*, FCC 06-144, WT Docket No. 02-60 (Sept. 29, 2006); FCC Adopts Pilot Program Under Rural Health Care Mechanism, *FCC News* Release (Sept. 26, 2006).

[9] The Advance Medical Technology Association ("AdvaMed") reported that the New England Healthcare Institute found that remote patient monitoring for congestive heart failure (the leading cause of hospital admissions for Americans over the age of 65) delivers significant savings on a number of fronts over standard care methods. Remote monitoring: (i) reduces patient rehospitalization rates by 32 percent. (ii) yields a total reduction of 132 patient days per 100 patients; and (iii) provides 25% net cost savings and a savings of $1,861 per patient over a six-month post-discharge period. *See Health Information Technology: Improving Patient Safety and Quality of Care* at 19, AdvaMed HIT White Paper, June 2005, *available at* http://www.advamed.org/policy/hit/hitwhitepaper.pdf *last accessed* Oct. 31, 2006.

[10] *See* Medtronic Petition for Rulemaking at 4-5.

The FCC's MedRadio rulemaking proceeding is appropriately focused on implanted, body-worn, and associated supporting medical RF devices "that serve to actively manage and maintain body functions and/or health conditions, and the spectrum needs and appropriate operational protocols for such devices."[11] Given this focus, the regulations that result from this process must proactively address the spectrum challenges that the next generation of wireless medical devices will face in light of the wide array of spectrum environments that the increasingly mobile patient will encounter.

A. Medtronic Strongly Supports The FCC's Proposal To Add The 401-402 And 405-406 MHz "Wing" Bands To The Existing Part 95 MICS Allocation.

Medtronic wholeheartedly supports the Commission's proposal to retain the "core" MICS allocation at 402-405 MHz[12] and to provide additional wireless medical capabilities in the two "wing" bands at 401-402 and 405-406 MHz.[13] Indeed, the FCC appropriately acknowledges that the wing bands are "well-suited for implanted and body-worn medical radio devices for the same reasons 402-405 MHz was originally designated for MICS."[14]

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[11] MedRadio NPRM at ¶ 5. Physicians may use the MedRadio service to collect data from and control external and internal patient medical devices, such as blood glucose sensors, insulin pumps, neural stimulators, and chronic pain control devices. Simple and useful Body Area Networks ("BANs") can be configured to perform therapeutic and diagnostic functions automatically.

[12] The Medical Implant Communications Service ("MICS") is an ultra-low power, mobile radio communication service that supports diagnostic and therapeutic functions associated with implantable medical devices. *See* Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band*, Report and Order*, 14 FCC Rcd. 21040, ¶¶ 6-8 (1999) ("MICS Report and Order").

[13] *See* MedRadio NPRM at ¶ 20 (wherein the Commission defines the 401-402 MHz and 405-406 MHz bands as the "wing" bands and the existing 402-405 MHz MICS band as the "core" portion of the proposed MedRadio band).

[14] *See* Med Radio NPRM at ¶ 20. These compelling reasons also were presented in Medtronic's Petition for Rulemaking. *See* Medtronic Petition for Rulemaking at 12-14; *see also* MICS Report and Order.

First, the proposed MedRadio band lies within a relatively low noise portion of the spectrum, as the only incumbent operations in the U.S. are the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services (collectively "METAIDS"). The low ambient noise characteristics of the 401-406 MHz band make it ideal for medical implant and related technologies that must operate with very low radiated power levels.

Second, signals in the 401-406 MHz frequency band propagate acceptably through and around human tissue.[15]

Third, the band has already been recommended internationally for medical use under the mobile service allocation, and the Commission's proposal will encourage the international harmonization of the band.[16]

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[15] *See* IEEE 802.15 WPAN Low Rate Alternative PHY Task Group 4a (TG4a) website *available at* http://www.ieee802.org/15/pub/TG4a.html *last accessed* Oct. 31, 2006; specifically, the "Body Area Channel Modeling For IEEE 802.15.4a" Presentation at Slide 5 illustrates that 400 MHz operations are subject to much less attenuation than operations at 900 MHz and 2.4 GHz.

[16] *See* Med Radio NPRM at ¶ 20; ETSI TR 102 343 V1.1.1 (2004-07), Electromagnetic Compatibility And Radio Spectrum Matters (ERM), Ultra Low Power Active Medical Implants (ULP-AMI) Operating In The 401 MHz To 402 MHz And 405 MHz To 406 MHz Bands; System Reference Document. The ITU-R has determined that ultra-low-power medical systems such as those that the FCC is proposing do not pose a threat of interference to METAIDS systems at 401-406 MHz. *See* Recommendation ITU-R SA.1346, Sharing Between The Meteorological Aids Service and Medical Implant Communications Systems (MICS) Operating in the Mobile Service In the Frequency Band 401-406 MHz.

U.S. allocation of the expanded 401-406 MHz band for low-power RF medical devices would encourage worldwide harmonization of the service band. International harmonization will serve the public interest by offering the international traveler with implanted or body-worn medical device technology an enhanced degree of freedom by ensuring that the traveler can receive appropriate medical attention both at home and abroad. For medical device manufacturers, international compatibility would allow development costs to be spread among multiple national markets. Economies of scale are directly reflected in lower medical cost.

Fourth, RF circuitry that operates within the wing bands of the MedRadio service can be designed for low-power operation using small antennas as required by implanted and body-worn medical devices.

Finally, the "provision of contiguous spectrum will provide for the maximum efficiency of design and operation"[17] for Body-Area Networks ("BANs") comprised of both implanted MICS devices and body-worn medical devices operating in the wing bands.[18] Indeed, the technology developed for MICS will undoubtedly prove useful in the development of MedRadio devices.

1. The MedRadio Rules Must Incorporate The Spectrum Sharing Requirements Set Forth In The MICS Regulations And Medtronic's Petition for Rulemaking.

In the MedRadio NPRM, the FCC has wisely affirmed that the core 402-405 MHz MICS allocation should be preserved for medical devices that listen before transmit ("LBT") and support adaptive frequency agility ("AFA") to "protect their function and to reduce the risk that they would be subject to interference," especially as RF medical device "spectrum use intensifies."[19] Medtronic strongly concurs with the FCC's decision to "preserve [the initial MICS] block of spectrum at 402-405 MHz for the more critical devices … that employ

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[17] MedRadio NPRM at ¶ 20.

[18] BANs can "synergize the information from multiple sensors, warn the user in the case of emergencies, and provide feedback during supervised recovery or normal activity. Candidate applications include post-stroke rehabilitation, orthopaedic rehabilitation …, and supervised recovery of cardiac patients." These systems also can be used for "analysis of balance and monitoring of Parkinson's disease patients … , computer supervision of health and activity status of elderly, weight loss therapy, obesity prevention, or in general promotion of a healthy, physically active, lifestyle." *See, e.g.*, Emil Jovanov, *et al*. *A Wireless Body Area Network Of Intelligent Motion Sensors For Computer Assisted Physical Rehabilitation*, Mar. 1, 2005, JOURNAL OF NEUROENGINEERING AND REHABILITATION, *available at* http://www.jneuroengrehab.com/content/2/1/6 *last accessed* Oct. 31, 2006.

[19] MedRadio NPRM at ¶ 24.

frequency monitoring both to protect their function and to reduce the risk that they would be subject to interference."[20]

As the Commission has found, there is no reason to upset the existing rules that apply to the 402-405 MHz core MICS band, for the RF medical implant industry is "still in its nascent stages."[21] Notwithstanding, the core MICS band already has emerged as the worldwide standard for active medical implant communications. The European Union and the European Free Trade Association countries, Australia, New Zealand, Japan, and Canada[22] have adopted regulations generally consistent with the FCC's MICS rules, which have been in place since 1999.[23] Thus, extensive research and development on 402-405 MHz medical device technology has taken place on a worldwide basis in reliance on these rules, in place since 1999, and there will soon be a host

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[20] MedRadio NPRM at ¶ 24.

[21] MedRadio NPRM at ¶ 24.

[22] *See* European Standard ETSI EN 301 839 V1.1.1 (2002-06), *Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio Equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 1* at 29-38; Australia Radiocommunications (Low Interference Potential Devices) Class Licence 2000 (No. 1), July 26, 2006 *available at* http://www.acma.gov.au/ACMAINTER.1900810:STANDARD::pc=PC_297 *last accessed* Oct. 31, 2006; Short Range Devices Discussion Paper, Summary of Submissions and Conclusions, Dec. 2004, New Zealand Ministry of Economic Development, Radio Spectrum Policy and Planning, *available at* http://www.med.govt.nz/rsm/planning/srd/submissions-summary/submissions-summary.pdf *last accessed* Oct. 31, 2006 (proposing to allocate 402 to 405 MHz for low-power biomedical telemetry applications); Japan Cabinet Order for Enforcement of the Radio Law at Art. 6, ¶ 4, item 2-(4) (Cabinet Order No. 245 of 2001) (added frequency of Specified Low-Power Radio Station) *and* Japan Ordinance Regulating Radio Equipment at Art. 49-14, ¶ 1, item 2 (Radio Regulatory Commission Rules No. 18 of 1950) (added technical conditions for self-contained medical data transmission systems); Active Medical Implant Communications System Devices in the 402-405 MHz Band, Industry Canada, Spectrum Management and Telecommunications Policy, Radio Standards Specification, RSS-243, Issue 2, Nov. 2005 *available at* http://strategis.ic.gc.ca/epic/internet/insmt-gst.nsf/vwapj/rss243e.pdf/$FILE/rss243e.pdf *last accessed* Oct. 31, 2006.

[23] *See* MICS Report and Order.

of medical implant devices that take full advantage of the core band's ability to support time-sensitive, life-critical communications.[24]

In concert with both the MICS regulations and Medtronic's Petition for Rulemaking, the FCC's proposed regulations for the wing bands "are designed to ensure compatibility among multiple uncoordinated" medical devices in close proximity.[25] Thus, Medtronic fully supports the Commission's proposal to allow implantable and body-worn medical devices as well as associated control and monitoring equipment to operate in the wing bands at 401-402 and 405-406 MHz without LBT or AFA in a way that both allows those devices to operate effectively and protects other devices from interference. Specifically, Medtronic agrees with the Commission that RF medical devices in the wing bands should limit their power to 250 nanowatts and operate with a 0.1% duty cycle during any one-hour interval (that is, 3.6 seconds of total transmission time within any one-hour period).[26] As the FCC has found, these limitations "reflect a reasonable balance between the operational capabilities needed for such devices to function properly and the need to minimize the risk of interference" to other devices in the wing bands.[27] In this way, the new service will allow medical professionals and their patients "to utilize

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[24] MedRadio NPRM at ¶ 24. Zarlink Semiconductor, Cambridge Consultants and AMI Semiconductor have announced the availability of MICS integrated circuit ("IC") smart radio transceiver designs supporting LBT and AFA. *See* Medtronic Petition for Rulemaking at 9-10; Zarlink Comments on Medtronic Petition. These companies' investments in MICS smart transceiver designs and the associated lessons learned will prove useful in the development of ICs compliant with the forthcoming MedRadio rules.

[25] MedRadio NPRM at ¶ 11.

[26] MedRadio NPRM at ¶ 25.

[27] MedRadio NPRM at ¶ 25.

potential life-saving medical technology without causing interference to other users of the spectrum."[28]

Medtronic agrees that it is not within the Commission's area of expertise to "define operating criteria" based upon whether particular devices should be "used for life-critical applications."[29] However, as the Commission acknowledges, it is within the agency's purview to make sure that medical device manufacturers that use RF signals to transmit time-sensitive or life-critical information are made aware of the inherent risks caused by the dynamic and unpredictable environments in which such communications systems will operate. To that end, Medtronic agrees with the Commission that it should adopt regulations for low-power wireless communications, that "proactively avoid … interference between various [unrelated] medical radio devices, as well as with non-medical devices [e.g., METAIDS] sharing the same spectrum, before they occur,"[30] as it has done with MICS.

2. The MedRadio Rules Should Incorporate The Other Technical Proposals For Operations In The Wing Bands As Set Forth In Medtronic's Petition for Rulemaking.

The FCC should authorize operations in the wing bands according to the technical proposals set forth in Medtronic's Petition for Rulemaking.

Maximum Authorized Emission Bandwidth In Wing Bands. The maximum authorized emission bandwidth for operations in the 401-402 and 405-406 MHz wing bands should be 100 kHz, as it would provide at least twenty communication "channels," which are needed to accommodate the expected proliferation of body-worn devices. METAIDS radiosondes, with

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28 MedRadio NPRM at ¶ 7.

29 MedRadio NPRM at ¶ 29.

30 MedRadio NPRM at ¶ 38.

whom a MedRadio device will share spectrum, have an emission bandwidth of approximately 300 kHz and a low-accuracy frequency reference. With a 100 kHz wing band emission bandwidth, a significant number of non-blocked "channels" would be available in the event a radiosonde drifts into one wing of the MEDS allocation. Thus, a 100 kHz maximum emission bandwidth would support a large number of transmitting devices, each with a sufficiently high data rate, in close proximity.

Emissions from Wing Band Into Core Band. The Commission also requested a technical rationale from those "supporting emission limits other than those currently in the [MICS] rules."[31] Operations in the wing bands are expected to support a variety of uncoordinated and coordinated implantable and body-worn sensors and other medical devices. This device proliferation will degrade performance of core band operations systems if wing band devices are permitted to inject high levels of out-of-band ("OOB") emissions into the core 402-405 MHz band. The fundamental technical issue is the proximity of wing band transmitters at 401-402 and 405-406 MHz in body-worn applications relative to implanted receivers, and the potential of OOB emissions from wing band devices to disrupt low-level critical transmissions from implantable device programmer/controllers to implants.

Field Strength Reduction for Body-Worn Devices. Medtronic proposed reducing the measured field strength for body-worn transmitters by 4 dB to account for body absorption of radiated power that occurs with this type of transmitter. Handheld and body-worn devices will have a reduced effective power output level due to absorption of RF energy by body tissue. When measuring these devices on an Open Area Test Site ("OATS"), one way to account for the

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[31] MedRadio NPRM at ¶ 21.

absorption of RF energy that occurs during normal usage is to reduce the measured level by a certain amount. Typically, 4 dB has been used to account for the reduction in radiated power.[32]

The FCC may prefer an alternative approach (which also would be acceptable to Medtronic) similar to that used to account for body absorption of implanted devices in Part 95 of the FCC rules. For body-worn and handheld devices, a torso simulator filled with appropriate tissue substitution material could be used with provision for mounting the medical device on the outside surface of the container near the vertical midpoint. ETSI has adopted this alternative approach.[33]

B. Body-Worn Devices That Will Operate In The Wing Bands Can Use LBT/AFA Or The Low-Power, Low-Duty Cycle Communications Mode To Support New Medical Applications.

The FCC sensibly proposed to allow body-worn devices to operate in the wing bands so long as they comply with the LBT/AFA requirements (that also apply to core-band communications) or the low-power, low-duty-cycle ("LPLDC") operational mode (that applies to wing band operations exclusively).[34] The Commission currently allows body-worn devices in

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[32] For example, if the data measured without using a tissue simulator near the equipment under test showed a field strength 2 dB over the limit, these readings would be corrected by subtracting 4 dB such that the actual field strength for purposes of compliance testing would be 2 dB under the limit, which is what would be expected had the equipment been operating in close proximity to a person. This same approach has been used by the FCC in evaluating devices such as wireless microphones, which have transmitting antennas in close proximity to the body of the user. *See* FCC OCE Bulletin 19, *FCC Test Procedure for Wireless Microphones and Auditory Assistance Devices*. If a tissue simulator is employed, however, the 4 dB correction would not be used.

[33] *See* EN 300 220-1, v.2.0.1.

[34] MedRadio NPRM at ¶ 25. In this regard, Medtronic supports the FCC's proposal to define a body-worn transmitter that would operate in the 401-402 and 405-406 MHz wing bands as a "transmitter intended to be placed on or in very close proximity (i.e., 6 centimeters or less) to the human body used to facilitate communications from a medical body-worn or implanted device." MedRadio NPRM, App. B, § A n.83. The proposed regulations for the wing bands will (Continued)

the core 402-405 MHz MICS band so long as they support LBT/AFA and comply with the definition of a MICS programmer/controller.[35]

The MICS regulations and the proposed rules for the 401-402 and 405-406 MHz bands are aimed at supporting different, but often complementary, medical devices. Unlike most medical devices that are expected to operate in the wing bands, implantable medical devices operating in the core MICS band have far greater battery constraints. Given that wireless implantable medical devices must use the same power source for therapeutic and diagnostic operations as they use for communications, conserving implant battery life is critical. To limit power drain, RF-capable implantable medical devices must use transmit power levels that are substantially less than the maximum allowed levels and having a quiet channel is critical to successful communications.

In addition, restoring implantable medical device functions when the battery becomes depleted is not simple and entails more risk to the patient than replacing batteries in body-worn devices. Batteries that power external body-worn devices generally are readily accessible and replaceable by the patient. Battery replacement in implantable medical devices, on the other hand, requires major surgery and usually involves replacing the entire device.

As the FCC recognizes in the MedRadio NPRM, the regulatory structure for low-power wireless medical communications should foster an environment in which those devices with such power constraints that can least afford frequent battery replacements are operated in a manner

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support advanced medical devices that make extensive use of the spectrum as well as simple medical sensor devices that operate on a transmit-only basis.

[35] MedRadio NPRM at ¶ 20. The MICS rules define a "Medical implant programmer/control transmitter" as a "MICS transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver connected to a medical implant device." 47 C.F.R. Part 95, Subpart E, Appendix 1.

that minimizes power consumption.[36] LBT and AFA must be utilized exclusively in the core MICS band to minimize the probability of receiving interference, for interference that makes an implantable medical device seek another channel for operation causes additional battery power drain (and delays communications).[37] Hence, the current MICS framework is appropriately structured to provide both for efficient spectrum management and minimal expenditure of precious battery power by implantable medical devices.

Unlike the core MICS framework, the proposed regulations for operation in the 401-402 and 405-406 MHz wing bands are appropriately designed to support devices with varying communications reliability requirements. The expenditure of power for body-worn sensor technologies, which would make extensive use of the wing bands, does not exact the same high price in terms of replacement expense and patient risk that replacement of batteries for implantable medical devices entails. However, unlike other wireless operations on an unlicensed or non-exclusive licensing basis where failure of the communications link due to any reason (interference or excessive ambient signal levels) can be overcome by continued retry until successful, a spectrum access protocol is still required to support a necessary level of communications reliability for short range medical applications.

There is no question that wireless medical technologies need self-regulating spectrum management techniques that limit interference, enable reliable channel access in unused

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[36] MedRadio NPRM at ¶ 24.

[37] "For a medical communication scheme to be usable, it must be both reliable and timely." *Ex Parte* Letter of Steven Greenberg, M.D., ET Docket No. 03-92, Dec. 13, 2003 (filed Jan. 8, 2004). Interference to time-sensitive communications from medical implants could delay emergency care with potentially fatal consequences. For instance, when a defibrillator with LBT and AFA capabilities is being implanted an RF communication channel typically will be obtained at the start of the surgical procedure. In this case, "a reliable communication scheme is critical if the operation of the implanted device must be modified to respond to an episode of ventricular fibrillation." *Id*.

spectrum, and support multiple uncoordinated medical devices in environments where there are a high concentration of patients in close quarters, such as hospitals, nursing homes, and assisted living environments. As medical professionals increasingly take advantage of the ease of use and effectiveness of wireless connectivity, their primary focus must be on the administration of therapy to patients and the analysis of medical data from patient devices. The spectrum management techniques set forth in the NPRM will ensure beneficial use of this limited amount of short-range wireless medical spectrum well into the future.

II. THE MEDRADIO SERVICE WOULD SUPPORT AN IMPORTANT COMPONENT OF THE PRESIDENT'S HEALTH INFORMATION TECHNOLOGY AGENDA.

The proposed MedRadio allocation is fully consistent with the President's Health Information Technology ("Health IT") agenda, as it would improve healthcare and contribute to $77 billion in medical healthcare savings.[38] The Administration is working hard to expand the use of Health IT to increase efficiency and minimize medical errors while protecting patients' personal information. In 2004, President Bush launched an initiative to make electronic health records available to most Americans by 2014. And, this past summer, the President issued another Executive Order to "ensure that health care programs administered or sponsored by the Federal Government [e.g., Medicare] promote quality and efficient delivery of health care through the use of health information technology."[39]

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[38] *See* RAND Corporation, *Health Information Technology: Can HIT Lower Costs and Improve Quality?* Sept. 2005, *available at* http://www.rand.org/publications/RB/RB9136/ *last accessed* Oct. 31, 2005 (estimating that annual savings from Health IT efficiency gains alone could amount to $77 billion). The RAND Corporation conducted a detailed study confirming that properly implemented Health IT would substantially lower healthcare costs and significantly improve quality.

[39] Exec. Order: *Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs*, § 1, Aug. 22, 2006, *available at*

(Continued)

Aside from the innovative medical applications that will improve the level of care to patients, the new service would lower considerably the huge administrative costs of providing medical care. In particular, wireless communications links can be used to integrate patient medical data from body-worn and implantable medical devices into the electronic patient record. Also, medical personnel will be able to retrieve data from patient devices upon arrival at the physician's office or hospital emergency room. These capabilities will avoid dangerous medical errors[40] and lower substantially the amount of paperwork and time spent recordkeeping and managing information in hospitals and physicians' offices – goals that President Bush has specifically identified in his forward-looking plan.[41] "The potential advantages are enormous: having a cradle-to-grave view of a patient will allow doctors to focus on preventive care, rather than just treating diseases. For employers, insurance companies, and the government, electronic medical records promise to help reduce skyrocketing health care costs, which now come to US $1.9 trillion, or about 16 percent of gross domestic product."[42]

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http://www.whitehouse.gov/news/releases/2006/08/20060822-2.html *last accessed* Oct. 31, 2006.

[40] *See* Robert N. Charette, *Dying For Data*, IEEE SPECTRUM at 22, Oct. 2006 ("[I]n the United States alone, an estimated 98 000 deaths occur annually from medical mistakes, and 1.5 million people suffer from adverse drug interactions, incorrect doses, and other medication errors. Many of these deaths and injuries could be avoided if the full medical records of patients were available to their treating physicians."); *see also* Milt Freudenheim, *Doctors Join to Promote Electronic Record Keeping,* N.Y. TIMES, Sept. 19, 2005 ("Electronic records, particularly ones that can be shared online by different doctors and hospitals, can improve the quality and safety of patient care by reducing errors that kill tens of thousands of patients each year.").

[41] *See A New* Generation *of American Innovation*, Apr. 26, 2004 at 1, in President Bush's Technology Agenda: Promoting Innovation and Competitiveness, *available at* http://www.whitehouse.gov/infocus/technology/ *last accessed* Oct. 31, 2006. As the President explained in his 2004 State of the Union Address: "By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care." *Id*. at 7.

[42] Charette, *Dying for Data*, *supra*.

III. FCC AND FDA COLLABORATION IS NEEDED TO LIMIT ADVERSE EMI EFFECTS ON MEDICAL DEVICES.

The FCC and the Food and Drug Administration ("FDA") should work together to manage the impact of electromagnetic interference ("EMI") on medical devices.[43] As noted in the MedRadio NPRM, implantable and body-worn devices can be "adversely affected" when they are brought into "unpredictable electromagnetic environments, both within and beyond the health care setting."[44] RF medical device operation can be impacted by medical equipment and other electronic devices, such as MRIs, X-ray equipment, and electronic article surveillance systems. In addition, patients with implanted or body-worn devices have increased susceptibility when they "congregate in a health care facility, resulting in a particularly high local density of use."[45]

To address EMI issues, FCC/FDA interaction should include FDA representatives from the agency's Center for Devices and Radiological Health ("CDRH") with expertise in the approval of active implantable medical devices. CDRH is intimately familiar with EMC issues specific to implantable medical devices and is keenly aware that the human safety RF exposure standards and regulations, which are intended to avoid biological effects from RF energy, do not ensure electromagnetic compatibility ("EMC") among emitting equipment and pacemakers or implantable cardioverter-defibrillators ("ICDs"). In fact, Medtronic's calculations show that an RF emitter producing field strength levels at or below human safety exposure standards can still adversely affect operations of these medical devices.

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[43] In addition, the FCC and FDA should make clear that medical devices that incorporate RF communications systems must be approved by both agencies before the devices may be lawfully marketed. MedRadio NPRM at ¶ 48.

[44] MedRadio NPRM at ¶ 45.

[45] MedRadio NPRM at ¶ 45.

A pacemaker or ICD that is subjected to high levels of EMI may exhibit various unanticipated responses, some of which are clinically significant and possibly life threatening. Take the case of a patient whose life depends on the proper operation of a pacemaker. In certain environments, the pacemaker may mistakenly sense high levels of EMI as cardiac activity and inhibit operation of the pacemaker, that is, stop pacing the heart, which can lead to dizziness, loss of consciousness or even death.

The FCC and FDA should work together, along with a medical device industry liaison, possibly the Advanced Medical Technology Association ("AdvaMed"), to analyze different methods of limiting the impact of EMI on medical devices and publish the studies and conclusions on their respective websites and in news releases. Some approaches to limiting EMI levels that should be explored include: (1) avoiding or filtering out certain frequencies, (2) reducing RF levels, (3) modifying modulation formats; and (4) limiting exposure time. As RF medical device technology evolves, this collaborative effort would inform FCC and FDA decisions involving EMC issues and ensure continued, successful operation of life-critical medical devices.

IV. THE COMMISSION SHOULD IDENTIFY SPECTRUM FOR FUTURE MEDICAL RADIO APPLICATIONS AND RECOGNIZE THE SPECIAL NEEDS FOR LIFE-CRITICAL USES.

Now is the time for the FCC to identify possible additional spectrum bands to support future advanced wireless medical uses, as the communications needs of medical devices will expand greatly in the coming years.[46] Because any additional spectrum allocation will be limited, the regulatory framework for such operations should be based on several key principles.

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[46] MedRadio NPRM at ¶ 36.

First, the FCC should design a regulatory framework that can support reliable communications of critical medical data. For example, nearly every patient who undergoes a major surgical procedure to obtain a medical implant does so because the patient needs the medical device to support certain life-critical functions. In undergoing such a serious procedure, the patient and the attending physician understandably expect the implant to operate reliably for a number of years before it will need to be replaced.[47] Time-sensitive communications from implanted medical devices, which include notification of life-threatening conditions as well as device operational status, must be successfully received and acted upon promptly, if not immediately. These communications call for an added degree of care.[48]

Second, the FCC should strongly encourage implementation of self-regulating spectrum management techniques, such as LBT and AFA, in order to relieve physicians and patients of the concerns associated with radio interference that can impact medical devices operating in close proximity. Indeed, as the Commission has repeatedly recognized, reliability in systems that carry safety-of-life communications is essential.[49]

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[47] Today's cardiac implants, for example, operate for five to seven years before replacement is required. And, in most cases where replacement is required, it is only because the implant's battery is depleted.

[48] For example, when a surgeon is implanting a pacemaker or a defibrillator and positioning leads to the heart or adjusting the implant's parameters while monitoring the physiological effects, the wireless communications link to the device must be low latency (typically less than 200 ms) so that the information from the electrocardiogram (ECG) is presented in (near) real-time. In cases where the duration of the interference exceeds the buffering capability of the system (which is directly related to the allowable link latency), life-critical, time-sensitive data can be lost.

[49] *See, e.g.*, Report to Congress On the Study to Assess Short-Term and Long-Term Needs for Allocations of Additional Portions of the Electromagnetic Spectrum for Federal, State and Local Emergency Response Providers, 14 FCC Rcd. 7772 (2005).

Third, to the extent that such operations will share spectrum with other users, wireless medical communications services should be licensed by rule to provide the necessary level of interference protection in relation to the other users.[50]

Fourth, the FCC should seek to allocate spectrum for wireless medical uses that may be compatible with international allocations, so that the international traveler with a medical device can receive comparable care when at home and abroad.

Fifth, the Commission should recognize that research and development of wireless medical equipment is much more costly and time-consuming than that associated with the typical RF device. In particular, the radio component of a medical device must be designed with an extremely high level of care, meet stringent reliability requirements and usage conditions, comply with a wide range of FDA regulations as well as FCC rules, and successfully complete lengthy clinical trials. As a result, the development timeframe is longer than that of the typical RF device.

Indeed, we are only now beginning to appreciate the first wave of devices that operate in the core 402-405 MHz MICS band, following years of R&D and successful compliance testing. These devices and others that make use of the RF circuits designed for MICS will support countless innovative medical applications well into the future.

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[50] MedRadio NPRM at ¶¶ 42-43. Thus, licensing by rule for such uses would be preferable to Part 15 unlicensed operation.

V. CONCLUSION

Medtronic strongly supports the Commission's proposal to allocate the two 1 MHz wing bands at 401-402 and 405-406 MHz for use by the next generation of body-worn and implantable RF medical devices. In addition, Medtronic firmly supports the FCC's plan to maintain the critically important interference avoidance protocols in the core 402-405 MHz band, as it evidences forward-looking and sensible spectrum policy. These protocols, which are technology neutral and foster equal sharing, are essential to support reliably the exponential growth in wireless medical applications over the coming decades. It is incumbent on the Commission to ensure that the broad range of medical applications and technologies on the horizon can successfully share the spectrum by limiting instances of interference blocking and corrupted data. The proposals in the Commission's MedRadio NPRM will do just that.

For these reasons, Medtronic urges the FCC to authorize operation of the next generation of RF medical devices in accordance with the proposals in the NPRM without delay.

Respectfully submitted,

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October 31, 2006

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